510(k) Summary

1. Submitter Information

Company name:	HMD BioMedical Inc.
Contact person:	Axel Lin
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Date Prepared:	Sep 17, 2014

2. Name of Device

Trade/Proprietary Name:

FIA Blood Glucose Monitoring System (Model no.: G2)

Common name:	Blood Glucose Test System
Classification name:	Glucose Test System
Classification Panel:	Clinical Chemistry (75)
Regulation no.:	862.1345 (Class II), 862.1660 (Class I)
Product code:	NBW, LFR, JJX, JQP

3. Predicate Device

Trade/Proprietary name:	PRECICHEK Cloudia Blood Glucose Monitoring System
Common name:	Blood Glucose Test System
Submitter:	HMD BioMedical Inc.
510(k) no.:	K120064
Product code:	NBW, LFR

Common name:	Glucose Control Solution
Submitter:	HMD BioMedical, Inc.
510(k) no.:	K032985
Product code:	JJX

4. Device Description

FIA Blood Glucose Monitoring System (G2) consists of:

(1) Glucose Meter

(2) Glucose Test Strips

(3) Two levels of glucose control solutions (L1 and L2) may be purchased separately. Glucose control solutions were previously cleared under K032985.

(4) Check Strip

(5) Instruction for use

[Test Principle]

FIA Blood Glucose Monitoring System (G2) is an electrochemical biosensor system that measures the amount of electric current produced then displays the result as a blood glucose level on the LCD monitor. When the blood is drawn into the blood reaction zone of the test strip, the glucose in the blood sample mixes with a special chemical in the test strip, which produces a small electric current. The reaction current is proportional to the amount of glucose in the blood. The result is displayed on the LCD monitor and automatically stored in the meter for future use.

[Control Solution]

The FIA Glucose control solution is intended for in vitro diagnostic use (i.e. for external use only) assessing the performance of the FIA Blood Glucose monitoring system (G2) and FIA Blood Glucose Test strips (G2). There are two levels of controls (L1 and L2).

[Check Strip]

The Check Strip can be used to check that the meter is operating properly. It is composed of PCB, resistor, top cover and bottom cover.

[Device Calibration]

The device is calibrated by implicit coding process. While inserting the test strip into strip slot to perform the blood glucose test, the coding procedure is complete. The meter will apply formula including this parameter of code to calculate the glucose value.

5. Intended Use

The FIA Blood Glucose Monitoring System (G2) is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood sample drawn from the fingertips only. The FIA Blood Glucose Monitoring System (G2) is intended to be used by a single patient and should not be shared.

The FIA Blood Glucose Monitoring System (G2) is intended for self testing outside the body (in vitro diagnostic use) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control. The FIA Blood Glucose Monitoring System (G2) should not be used for the diagnosis of or screening of diabetes or for neonatal use.

The FIA Blood Glucose Test Strips (G2) are for use with the FIA Blood Glucose Meter (G2) to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips only.

The FIA Glucose Control Solutions are for use with the FIA Blood Glucose Meter (G2) and FIA Blood Glucose Test Strips (G2) to check that the meter and test strips are working together properly and that the test is performing correctly.

6. Comparison of Subject Devices and predicate device

Technological Characteristics Comparison Table of FIA Blood Glucose Monitoring System (G2) and PRECICHEK Cloudia Blood Glucose Monitoring System (K120064)

Similarities		
Item	**Subject device** FIA BGMS (G2)	**Predicate device** PRECICHEK Cloudia BGMS (K120064)
Intended use	It is designed to quantitatively measure the concentration of glucose in fresh capillary whole blood.	Same
Detection method	Amperometry: Current produced by chemical reaction	Same
Test range	20~600mg/dL	Same
Operating conditions	50~104°F (10~40°C), 20~80%	Same
Autocoding	Yes	Same
Enzyme	Glucose Dehydrogenase (FAD) (Aspergillus oryzae)	Same
Capillary testing site	Fingertips only	Same
Sample volume	0.5ul	Same
Memory	999	Same
Test time	5 sec	Same
Time & date setting	Reload the batteries then press the buttons to set the time and date.	Same

Differences		
Item	**Subject device** FIA BGMS (G2)	**Predicate device** PRECICHEK Cloudia BGMS (K120064)
Data transmission	GSM	N/A
Average	N/A	7, 14, 21, 28 days

7. Discussion of Clinical Tests Performed

FIA Blood Glucose Monitoring System (Subject Device) is compliant to the standard of ISO 15197:2003 In vitro diagnostic test systems- Requirements for blood glucose monitoring systems for self-testing in managing diabetes mellitus. All the relevant activities were performed by professionals and the results demonstrated that the predetermined acceptance criteria were fully met.

8. Conclusion

The subject device was tested and fulfilled the requirements from those standards mentioned above, and it's concluded that the subject device is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

October 2, 2014

HMD BIOMEDICAL, INC.
AXEL LIN
MANAGER OF QUALITY ASSURANCE
#181 MINSHENG STREET, XINPU TOWNSHIP, HSINCHU COUNTY, TW 305
TAIWAN

Re: K131173
Trade/Device Name: FIA Blood Glucose Monitoring System (G2)
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: II
Product Code: NBW, LFR, JJX
Dated: September 5, 2014
Received: September 8, 2014

Dear Ms. Lin:

This letter corrects our substantially equivalent letter of September 25, 2014. We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Katherine Serrano -S

For: Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of *In Vitro* Diagnostics and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K131173

Device Name
FIA Blood Glucose Monitoring System (G2)

Indications for Use *(Describe)*
The FIA Blood Glucose Monitoring System (G2) is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood sample drawn from the fingertips only. The FIA Blood Glucose Monitoring System (G2) is intended to be used by a single patient and should not be shared.

The FIA Blood Glucose Monitoring System (G2) is intended for self testing outside the body (in vitro diagnostic use) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control. The FIA Blood Glucose Monitoring System (G2) should not be used for the diagnosis of or screening of diabetes or for neonatal use.

The FIA Blood Glucose Test Strips (G2) are for use with the FIA Blood Glucose Meter (G2) to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips only.

The FIA Glucose Control Solutions are for use with the FIA Blood Glucose Meter (G2) and FIA Blood Glucose Test Strips (G2) to check that the meter and test strips are working together properly and that the test is performing correctly.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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